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 Reply to Office action of October 25, 2005

Remarks:

Claims 1 to 35 remain in the application. Claims 1 to 12 and 26 to 33 are subject to examination and claims 13 to 25 have been withdrawn from examination. Claims 28, 34, and 35 have been amended.

Reconsideration of the application is requested.

In item 3 on page 2 of the above-identified Office action, claims 28, 34, and 35 have been rejected as failing to comply with the enablement requirement under 35 U.S.C. § 112, first paragraph. More specifically, the Examiner states that these "claims recite the limitation of releasably coupling the two arms to the bridge. However, the applicant has not provided any disclosure in the specification or drawing to support this limitation, i.e., as best understood by the examiner, the arms and bridge are integral/one-piece and not separable. Therefore, the claims are not enabled."

Applicants respectfully disagree with this rejection. As set forth in the claims, the arms have piercing portions and a portion of at least one of the arms (see FIGS. 21 to 24) separates from the bridge. Therefore, it can be said that the arms separate from the bridge. Nonetheless, in order to remove this rejection and even more clearly define the

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features of the claims, claims 28, 34, and 35 have been amended to provide that at least a part of a piercing portion separates from the respective arm to which it is connected. See page 26, for example, of the specification of the instant application.

It is accordingly believed that the specification and the claims meet the requirements of 35 U.S.C. § 112, first paragraph. The above noted changes to the claims are provided solely for the purpose of satisfying the requirements of 35 U.S.C. § 112. The changes are neither provided for overcoming the prior art nor do they narrow the scope of the claim for any reason related to the statutory requirements for a patent.

In items 5 and 6 on pages 3 to 4 of the above-identified Office action, claims 1 to 4 and 26 have been rejected as being fully anticipated by United States Patent No. 5,522,823 to Kuntz et al. (hereinafter "Kuntz") under 35 U.S.C. § 102.

As will be explained below, it is believed that the claims were patentable over the cited art in their original form and, therefore, the claims have not been amended to overcome the references.

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Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1 calls for, *inter alia*, a medical method including the steps of:

- a) advancing a clip over body tissue, said clip having two substantially parallel arms each having a respective piercing portion and a bridge coupling the two arms, such that said body tissue is located between said two arms and such that said clip applies force to said body tissue; and
- b) subsequently bending said piercing portion of at least one of said two arms through more than one half a thickness of said body tissue, said two arms remaining substantially parallel throughout the time said piercing portion of said at least one arm is bent.

Virtually every feature of claim 1 is not disclosed by Kuntz, and each will be discussed in turn.

Initially, however, the annotated FIG. 3 on page 4 of the rejection must be discussed.

Claim 1 provides two substantially parallel arms each having a respective piercing portion. In the present invention, arms 312, 314, 412, 414 are substantially parallel and each have a respective piercing portion 320, 322, 420, 422. As set forth, for example, on page 25, lines 17 to 20, each piercing portion "punctures the fundus twice substantially forming a circular fastener." Thus, when "piercing portion" is defined in the

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instant application, it means what is self-evident in the words used, the piercing portions pierce tissue.

The examiner clearly defines a first arm of the Kuntz clip as pin 9 and that the arm 9 has a "piercing portion" formed by its pointed end 10. The second "arm" of the Kuntz clip is defined as Kuntz's bridge portion 8. The Examiner defines the "piercing portion" of this "arm" as the totality of (1) projection 3, (2) the upper clip portion 2, (3) the opening 11, and (4) the "rounded protective nose 12." Kuntz at col. 3, lines 37 to 38. Nowhere in Kuntz is there any suggestion, hint, or even a glimmer of some disclosure that would let one having ordinary skill in the art be directed to having any of these four parts, and especially the "rounded protective nose 12," be used to pierce through tissue. In fact, if such were the case, then the Kuntz clip would not function! As shown in FIG. 3 of Kuntz, if the two "piercing portions" 10, 12 passed through tissue in this parallel configuration, then they could no longer function as Kuntz intended -- in other words, parallel piercing of tissue by these two "piercing portions" would completely eviscerate the ability of the Kuntz clip to have the piercing portion 10 pass through the opening 11 and be locked as shown in FIGS. 1A, 7, and 8. Accordingly, the Examiner's attempt to analogize any of these four parts (and especially the rounded protective nose 12) to the piercing

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portion 322, 422 of the invention of the instant application is problematic.

This conclusion is also true with respect to the "bridge" analogy. Contrary to the express disclosure in Kuntz that the portion 8 is the Kuntz bridge, the Examiner attempts to redefine the lower clip portion 1 as a bridge. As set forth herein, this labeling cannot withstand scrutiny.

Next, claim 1 requires "advancing two substantially parallel arms" "over body tissue." When the Kuntz clip is ready to grasp and engage a first tissue edge of two tissue edges to be secured together, the Kuntz "clip has to be opened at the location of its application." Kuntz at col. 8, lines 52 to 53 (emphasis added by applicants). "[T]he clip is opened by partial straightening of the hinge structure 48 as shown in FIG. 5." Id. at lines 64 and 65. FIG. 5 clearly shows that a configuration where two arms are substantially parallel to one another does not exist in the tissue engaging position illustrated in FIG. 5 of Kuntz. Accordingly, Kuntz does not disclose this second feature of claim 1.

Third, the two parallel arms of the clip of claim 1 must be advanced over the tissue "such that said clip applies force to said body tissue." When the Kuntz clip is being

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advanced over tissue, Kuntz clearly describes that it is must in the configuration shown in FIG. 5. In such an orientation, the tip 10 must be pierced through the tissue with the head 12 being separate from the tissue and not piercing any tissue. There is no disclosure or suggestion in Kuntz to support an argument that the two arms are applying force to tissue when the tip 10 is being pierced through tissue as shown in FIG. 5. Thus, Kuntz does not disclose this third feature of claim 1.

Fourth, claim 1 provides: "subsequently bending said piercing portion of at least one of said two arms through more than one half a thickness of said body tissue." Kuntz only discloses one piercing portion -- tip 10. This portion is not bent until after the clip has been entirely deployed as shown in FIGS. 7 and 8. At this time, the piercing tip 10 has already passed through the tissue. In contrast, claim 1 provides that the piercing portion must be bent through tissue. Nowhere does Kuntz disclose or suggest that the piercing tip 10 is, in any way, bent through tissue. It is only bent to lock the clip. See Kuntz at col. 9, line 39, to col. 10, line 39. Thus, Kuntz does not disclose this fourth feature of claim 1.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either

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show or suggest the features of claim 1. Claim 1 is, therefore, believed to be patentable over the art. Dependent claims 2 to 12 and 26 are believed to be patentable as well because they all are ultimately dependent on claim 1.

It is noted, however, that claim 4 requires bending both of the piercing portions of "both of said arms completely through said body tissue." Nowhere does Kuntz disclose or suggest bending the rounded nose 12 or the upper clip portion 2 through tissue. Thus, Kuntz does not disclose this feature of claim 4.

In item 11 on page 5 of the above-identified Office action, claims 5 to 12, 27, and 29 to 33 have been rejected as being obvious over United States Patent No. 6,086,600 to Kortenbach in view of Kuntz under 35 U.S.C. § 103.

As will be explained below, it is believed that the claims were patentable over the cited art in their original form and, therefore, the claims have not been amended to overcome the references.

Insofar as claims 5 to 12 are dependent upon claim 1, and due to the fact that claim 1 is believed to be allowable as set forth above, these dependent claims are also believed to be

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allowable. Thus, it is believed that further argument with regard to these claims is unnecessary.

Claim 27 provides, *inter alia*, a medical method, including the steps of:

providing a clip having two substantially parallel arms each having a piercing portion and a bridge coupling the two arms;

folding body tissue to form a folded portion extending along a longitudinal direction;

advancing the clip over the folded portion of body tissue in the longitudinal direction to place the folded portion between the two arms and to apply force to the folded portion with the clip; and

bending the piercing portion of at least one of the two arms through more than one half a thickness of the folded portion at an angle to the longitudinal direction, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

Claim 29 provides, *inter alia*, a medical method, including the steps of:

providing a clip having two substantially parallel arms each having a respective piercing portion and a bridge coupling the two arms;

advancing a clip over body tissue folded on itself to form a first portion of a fold and a second portion of the fold such that the first and second portions are located between the two arms and such that the clip applies force to the body tissue; and

subsequently bending the piercing portion of at least one of the two arms through the first portion

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of the **fold** and at least partially through the second portion of the fold, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

Claim 31 provides, *inter alia*, a method for medically clipping body tissue, including the steps of:

providing a clip having two substantially parallel arms and a bridge coupling the two arms, the two arms each having a respective piercing portion;

advancing a clip over body tissue folded on itself to form first and second portions of a fold disposed between the two arms and to apply a force to the folded body tissue, the folded tissue defining a longitudinal direction of the folded body tissue, the **piercing portions of the two arms being initially oriented along the longitudinal direction;** and

subsequently bending the piercing portion of at least one of the two arms to pierce through the first portion of the folded body tissue and at least partially through the second portion of the fold at an angle to the longitudinal direction, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

Claim 32 provides, *inter alia*, a method for medically clipping body tissue, including the steps of:

providing a clip having two substantially parallel arms and a bridge coupling the two arms, the two arms each having a respective piercing portion;

advancing a clip over body tissue folded on itself to form first and second portions of a fold disposed between the two arms and to apply a force to the folded body tissue, the folded tissue defining a longitudinal direction of the folded body tissue,

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the **piercing portions of the two arms being initially oriented along the longitudinal direction;**
and

subsequently bending the piercing portion of at least one of the two arms at an angle to the longitudinal direction to pierce through the first portion of the folded body tissue and at least partially through the second portion of the fold, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

Claim 33 provides, *inter alia*, a medical method, including the steps of:

a) **advancing a clip over two thicknesses of body tissue**, said clip having two substantially parallel arms each having a respective piercing portion and a bridge coupling the two arms, such that said body tissue is located between said two arms and such that said clip applies force to said body tissue;
and

b) **subsequently bending said piercing portion of at least one of said two arms through more than one of said thicknesses of said body tissue**, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

The features in these claims are similar to the features set forth with regard to claim 1 above and, therefore, the arguments above are hereby incorporated herein in their entirety and are not duplicated below.

As for claims 27, 29, and 33, Kuntz does not disclose applying force to a folded portion of tissue as the clip is advanced

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over the tissue. Nor does Kuntz teach bending a piercing portion through tissue after the clip is applying force to the tissue when advanced thereover.

With regard to claims 29 and 32, Kuntz does not disclose applying force to a folded portion of tissue as the clip is advanced over the tissue or having the piercing portion be initially oriented along the longitudinal direction of the tissue. In fact, Kuntz is silent with regard to directionality of tissue when being pierced by the Kuntz clip. Kuntz also does not teach bending a piercing portion through tissue after being advanced over the folded tissue where the piercing portion is at an angle to the longitudinal direction for a second portion of the folded tissue.

In these independent claims, two substantially parallel arms of a clip must be advanced over body tissue with each of the arms having a respective piercing portion and applying a force on the tissue therebetween, and a piercing portion must be bent thereafter through the body tissue while the two arms remain parallel. As set forth above, Kuntz does not disclose or suggest these features. This is also true for Kortenbach. The Examiner combines Kortenbach with Kuntz merely for teaching the fastening of fundus tissue. Kortenbach's combination with Kuntz, therefore, does not make up for the

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deficiencies of Kuntz to anticipate the features of the instant claims (as set forth above in detail with respect to claim 1, for example).

Additionally, in some of these independent claims, a "longitudinal direction" of the tissue is defined with piercing portions being oriented initially along such a direction where the piercing portion is bent at an angle to that direction. Neither Kortenbach nor Kuntz describe or suggest such features.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation in the prior art to make the selection made by the applicant". Interconnect Planning Corp. v. Feil, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". In re Bond, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990) (emphasis added). "Under Section 103 teachings of references can be combined only if there is some suggestion or incentive to do so." ACS

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Hospital Systems, Inc. v. Montefiore Hospital et al., 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original).
 "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, **the showing of combinability, in whatever form, must nevertheless be 'clear and particular.'**" Winner Int'l Royalty Corp. v. Wang, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Applicants believe that there is no "clear and particular" teaching or suggestion in Kuntz to incorporate the features of Kortenbach, and there is no teaching or suggestion in Kortenbach to incorporate the features of Kuntz.

In establishing a *prima facie* case of obviousness, it is incumbent upon the Examiner **to provide a reason why** one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicants' disclosure. See, for example,

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175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999).

Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious

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Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), cert. den., 488 U.S. 825 (1988). The Examiner has not provided the requisite reason why one of ordinary skill in the art would have been led to modify Kuntz or Kortenbach or to combine Kuntz's and Kortenbach's teachings to arrive at the claimed invention. Further, the Examiner has not shown the requisite motivation from some teaching, suggestion, or inference in Kuntz or Kortenbach or from knowledge available to those skilled in the art.

The Examiner has not met this burden by providing such particular findings. Specifically, the three sentences on page 5 of the Office action describing the combination do not cite any support in either reference sufficient to support the Examiner's conclusions. Upon evaluation of the Office action, it is respectfully believed that the "evidence" adduced is insufficient to establish a *prima facie* case of obviousness with respect to the claims.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the

time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See In re Dembiczak,

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